



THE ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

**MAY 17 2016**

The Honorable Shaun L.S. Donovan  
Director  
Office of Management and Budget  
Executive Office of the President  
Washington, D.C. 20503

Dear Mr. Donovan:

I am responding to the Office of Management and Budget's request for the U.S. Environmental Protection Agency's views on enrolled bill S. 1523, which is legislation to reauthorize the National Estuary Program.

The agency believes that the National Estuary Program is a proven, effective program that merits a continued commitment to ensure further improvement of the nation's estuaries.

I recommend that the President sign this legislation.

Should you have any questions or require additional information, please contact me or your staff may contact Denis Borum, my colleague in the Office of Congressional and Intergovernmental Relations, at (202) 564-4836 or [borum.denis@epa.gov](mailto:borum.denis@epa.gov).

Thank you for the opportunity to share my thoughts on this bill.

Sincerely,

A handwritten signature in black ink, appearing to read "Gina McCarthy", is written over the typed name.

Gina McCarthy



THE ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUN 08 2016

The Honorable Shaun L.S. Donovan  
Director  
Office of Management and Budget  
Executive Office of the President  
Washington, D.C. 20503

Dear Mr. Donovan:

I am responding to the Office of Management and Budget's request for the U.S. Environmental Protection Agency's views on enrolled bill H.R. 2576, the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act.

The agency believes that this legislation makes significant improvements to modernize and strengthen the nation's chemical safety laws. It provides the tools necessary to ensure public safety and achieve global leadership in chemicals management.

I recommend that the President sign this legislation.

If you have any questions, please contact me or your staff may contact Sven-Erik Kaiser in the EPA's Office of Congressional and Intergovernmental relations at [kaiser.sven-erik@epa.gov](mailto:kaiser.sven-erik@epa.gov) or (202) 566-2753.

Sincerely,

A handwritten signature in black ink, appearing to read "Gina McCarthy", is written over the typed name.

Gina McCarthy

# TOXIC SUBSTANCES CONTROL ACT (TSCA) REFORM

## BACKGROUND AND HIGHLIGHTS

### ADMINISTRATION'S PRINCIPLES FOR TSCA REFORM

In 2009, the Administration expressed its goals for reform legislation in terms of the following principles:

- *Chemicals Should be Reviewed Against Safety Standards that are Based on Sound Science and Reflect Risk-based Criteria Protective of Human Health and the Environment.*
- *Manufacturers Should Provide EPA with the Necessary Information to Conclude That New and Existing Chemicals are Safe and Do Not Endanger Public Health or the Environment.*
- *Risk Management Decisions Should Take into Account Sensitive Subpopulations, Cost, Availability of Substitutes and Other Relevant Considerations.*
- *Manufacturers and EPA Should Assess and Act on Priority Chemicals, Both Existing and New, in a Timely Manner.*
- *Green Chemistry Should Be Encouraged and Provisions Assuring Transparency and Public Access to Information Should Be Strengthened.*
- *EPA Should Be Given a Sustained Source of Funding for Implementation.*

### STATUS OF LEGISLATION

The Senate introduced the Frank R. Lautenberg Chemical Safety for the 21st Century Act (S.697) on March 10, 2015, and passed an amended version on voice vote on December 17, 2015. The House passed its legislative proposal, the TSCA Modernization Act of 2015 (H.R. 2576), with a 398-1 vote on June 23, 2015. In the ensuing months, House and Senate staff, with technical assistance from EPA, merged the two proposals into a compromise bill. The House passed the amended bill with a 403-12 vote on May 24, 2016. The Senate passed the House version by voice vote on June 7, 2016.

### HIGHLIGHTS OF THE FINAL AGREEMENT

The following summarizes some of the key provisions in the final bill:

#### EXISTING CHEMICALS

**PRIORITIZATION PROCESS.** For existing chemicals, the bill requires EPA to establish a risk-based prioritization process under which existing chemicals are prioritized into "high-priority" and "low-priority" substances. Designation as a "high-priority" triggers a mandatory review of the chemical by EPA, and enforceable statutory deadlines. There are no such deadlines or review requirements in current law.

**TESTING AUTHORITY.** The bill provides EPA with new authority to more expeditiously require manufacturers to develop chemical information via order and consent agreement. Existing law provides this authority only by rule. The bill also expands the grounds upon which EPA

can require testing, including new testing authority when necessary for prioritizing chemicals or conducting risk evaluations.

**ANIMAL TESTING.** The bill aims to reduce testing on vertebrate animals by requiring EPA to identify scientifically reliable and relevant alternatives to vertebrate animal testing and develop a strategic plan to promote development and implementation of such alternatives.

**DEADLINES FOR REVIEW OF PRIORITY CHEMICALS.** Once designated as a “high-priority” substance, the bill requires that a chemical risk evaluation be completed **within** three years, with an extension of up to six months. EPA must have 10 ongoing risk evaluations within 180 days of enactment. The number must increase to 20 ongoing risk evaluations within three and a half years of enactment, with a minimum one-off-one-on replacement of chemicals as risk evaluations are completed.

**RISK-BASED STANDARD.** The bill effectively shifts to a purely risk-based standard, meaning that a determination of whether a chemical presents an “unreasonable risk” is made without consideration of costs and other non-risk factors. EPA must also explicitly consider risks to susceptible and highly exposed populations during its evaluation. If an unreasonable risk is identified, EPA must take regulatory action to eliminate that risk. Although the bill requires EPA to consider costs and availability of alternatives when selecting among appropriate risk management options, cost considerations do not alter the underlying requirement to regulate the chemical so that it no longer presents the unreasonable risk found in the risk evaluation. Critical uses of the chemical, for which unreasonable risks cannot be avoided, can be addressed through an exemption process.

**MANUFACTURER INITIATED ASSESSMENTS.** The bill creates a process for manufacturers to petition EPA to review particular chemicals. For those EPA has already identified as priority chemicals on the TSCA Work Plan, manufacturers can petition for those chemicals to move to a risk evaluation, and pay 50 percent of the cost. For other chemicals not designated as high-priority, manufacturers can request that EPA conduct a request evaluation. Industry would pay 100 percent of the cost of those assessments. These chemicals do not count towards or otherwise limit the number EPA can designate as high priority, except that they must amount to a minimum of 25 percent (if EPA gets a sufficient number of valid requests) and a maximum of 50 percent of the cumulative total number of high priority chemicals. For example, if EPA is evaluating 20 high priority chemicals, there would be between 5 and 10 industry petitioned chemicals proceeding in parallel.

**DEADLINES FOR MANAGING CHEMICAL RISKS.** For any unreasonable risks identified, EPA must promulgate a rule to address the risk within two years of completing the risk evaluation, with an extension of up to two years. The aggregate of deadline extensions for the risk evaluation and risk management rule cannot exceed two years. Industry must comply with EPA’s risk management restrictions within the time period set by EPA, which is to be as soon as practicable but no more than five years after rule promulgation. In the case of an

outright ban or phase-out, the phase-out must begin no later than five years after the promulgation of the rule and be complete as soon as practicable thereafter.

**PERSISTENT, BIOACCUMULATIVE AND TOXIC (PBT) CHEMICALS.** The bill establishes a fast track process to address certain PBT chemicals that are already on EPA's TSCA Work Plan. At a minimum, risk management must reduce exposure to these substances to the extent practicable. Rules to address these chemicals must be proposed within three years of enactment and finalized 18 months later. Other specific requirements in the bill encourage prioritization of PBTs in the overall risk evaluation process.

## **NEW CHEMICALS**

**AFFIRMATIVE FINDING.** The bill requires EPA to make an affirmative finding on a new chemical, or a new use of an existing chemical, before it is allowed to enter the market. Current law allows manufacture to begin simply if the review period lapses without EPA taking any action.

**REGULATION OF ARTICLES.** The bill imposes a new requirement before EPA can require premarket notification and review for a new use of a chemical in an article. EPA must find that the notification is warranted based on "the reasonable potential for exposure through the article or category of articles."

**CONFIDENTIAL BUSINESS INFORMATION (CBI).** The bill establishes substantiation requirements for a manufacturer's claim that particular information submitted to EPA constitutes CBI, and requirements that EPA affirmatively review these claims – either universally (when chemical identity is claimed as CBI) or by screening a subset of submitted claims (in other cases). The bill also provides for retrospective review of whether older CBI claims involving chemical identity are adequately substantiated.

**SOURCE OF FUNDING.** The bill gives EPA authority to impose fees on chemical manufacturers and processors who: (1) are submitting test data; (2) are submitting a notification of their intent to manufacture a new chemical; (3) are requesting EPA to conduct a risk evaluation of an existing chemical; or (4) are manufacturing a chemical substance that is the subject of a risk evaluation (whether industry requested or not). EPA can use the fees to defray the cost of reviewing new and existing chemicals, and to cover expenses relating to CBI claims. In most cases, fees are set so as to defray 25 percent of these program implementation costs, subject to an annual cap of \$25 million. Fees for industry requested risk evaluations can be more comprehensive. They are not subject to the \$25 million cap. They are set to defray either 50 percent or 100 percent of EPA's costs, depending on whether the chemical was already on EPA's Work Plan or whether it is being reviewed solely at industry request.



## STATE-FEDERAL RELATIONSHIP

**PRESERVATION OF STATE LAWS.** The bill preserves state authority to act on any chemicals that EPA has not acted on, including particular uses of or risks from chemicals that EPA has not addressed. Even when EPA does act on a chemical, the following state actions are still preserved:

**STATE PROVISIONS THAT TOOK EFFECT BEFORE APRIL 22, 2016.** No preemption. The bill grandfathers state actions taken prior to this date. However, a state regulatory action taken after April 22, 2016, would be subject to preemption, even if it is implementing a state statute promulgated before that date, unless the state statute was in effect in August 2003 (e.g., California), in which case no preemption applies.

**OTHER STATE ENVIRONMENTAL LAWS.** Generally, no preemption. The bill preserves broader state environmental authorities that are not specifically targeted at chemical risk management and/or are authorized or approved by EPA under other federal environmental statutes (e.g., relating to air quality, water quality, or waste treatment and disposal). State reporting, monitoring or other information obligation requirements are generally also protected from preemption.

**IDENTICAL STATE/FEDERAL REQUIREMENTS.** No preemption. The bill allows the states and federal government to co-enforce identical regulations and both collect penalties, with the condition that the combined total state and federal penalties cannot exceed the federal statutory maximum.

**LOW-PRIORITY DESIGNATION.** No preemption. There is no preemption of state laws resulting from designation of a chemical as low-priority. Also, low-priority designations are judicially reviewable and can be challenged by any member of the public within 60 days.

**PREEMPTION OF STATE LAWS.** The bill preempts certain state statutes, criminal penalties and administrative actions to “prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance,” as described below:

**EPA FINDS THE CHEMICAL TO BE SAFE.** If the state provision took effect after April 22, 2016, the provision would be preempted upon EPA’s determination in a risk evaluation that the chemical does not present an unreasonable risk of injury to health or the environment. Unless a waiver or limited exception applies, or the provision implements a state statute in effect in August 2003, the state cannot continue to enforce the provision.

**EPA TAKES FINAL ACTION TO ADDRESS A CHEMICAL’S RISK.** Likewise, for a state provision that took effect after April 22, 2016, the provision would be preempted when EPA takes final action on a chemical to eliminate any unreasonable risks. Unless a waiver or limited exception applies, or the provision implements a state statute in effect in August 2003, the state cannot continue to enforce the provision.

**PAUSE PREEMPTION.** States seeking to put new provisions into effect *after* EPA has already defined the scope of a risk evaluation for a high-priority chemical under section 6(b)(4)(D) would be subject to a period of “pause preemption.” Pause preemption begins when EPA defines the scope of a risk evaluation and continues until the date on which EPA publishes the risk evaluation. In other words, new state action is “paused” by EPA’s ongoing risk evaluation on the chemical substance, unless a waiver or limited exception applies.

As described earlier, preemption continues if EPA finds that the chemical meets the safety standard. If EPA misses the deadline for completing the risk evaluation deadline, the pause preemption is automatically lifted. If EPA finds that the chemical does not meet the safety standard, the pause preemption is lifted, and a state could put a new provision into place while EPA develops the risk management rule. However, the state provision would then be preempted on the effective date of the EPA risk management rule.

Note that the chemicals not “prioritized” under section (b) would *not* be subject to pause preemption, including the initial 10 chemicals identified for risk evaluation, chemicals for which industry requests a risk evaluation, and PBT chemicals identified for expedited risk management under section 6(h).

**SIGNIFICANT NEW USE RULES.** The bill preempts any new or existing state significant new use rule for a chemical once EPA has imposed a comparable requirement, unless it qualifies for an exception or waiver.

**STATE WAIVERS FROM PREEMPTION.** Even if the bill would otherwise preempt a state action, the state action may continue if the criteria for one of the following exemptions are met:

**DISCRETIONARY EXEMPTIONS** pursuant to section 18(f)(1). These exemptions can only be issued via EPA rulemaking, and only if particular criteria are met, including a finding of “compelling conditions” and EPA support for the state’s scientific judgment of the risk.

**REQUIRED EXEMPTIONS** from pause preemption pursuant to section 18(f)(2). EPA must grant an exemption to pause preemption, upon application by a state if EPA determines all of the following: (1) the state requirement doesn’t violate federal law; (2) the state requirement doesn’t unduly burden interstate commerce; and (3) the state’s concern about the chemical substance or the use of the chemical substance is based in peer-reviewed science.

Separately, the bill mandates an exemption from pause preemption where a state has enacted a statute, finalized a rule, or has at least begun a state rulemaking process to address a chemical at the time EPA sets the scope for the federal risk evaluation of the same chemical. Accompanying changes to the prioritization and risk evaluation scoping deadlines in section 6 are aimed at giving states advanced notice of impending federal

action on a particular chemical, and would effectively guarantee a window of 12-18 months for states to take advantage of this exemption.

**DELEGATION.** Determinations on waiver requests are the Administrator's duty and are non-delegable.

**AUTOMATIC APPROVAL.** If EPA fails to make a decision on a state waiver request under section 18(f)(2) within the 110 day review period, the waiver is automatically approved.

**JUDICIAL REVIEW.** EPA's grant of an exemption under section 18(f)(1) or (2) can be challenged in court.

**MERCURY EXPORT AND DISPOSAL.** The bill amends the Mercury Export Ban Act (MEBA) and addresses the Department of Energy's responsibility to designate a long-term storage facility for elemental mercury. If the facility is not operational by January 1, 2020, the bill requires the Department of Energy to accept title to and pay applicable permitting and storage costs for mercury accumulated in accordance with MEBA prior to that date. The bill also requires EPA to create an inventory of supply, use, and trade of mercury and mercury compounds; and prohibits export of certain mercury compounds.

**CANCER CLUSTERS.** The bill provides authority and direction to appropriate federal agencies for the identification, designation, and investigation of cancer clusters – a high incidence of cancer within a population group, geographical area, and period of time.

**SKILLED NURSING FACILITIES.** Unrelated to TSCA or chemicals, the bill adds skilled nursing facilities to the list of health care providers for which universal telecommunications service must be provided. This provision would take effect 180 days after enactment.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OCT 15 2018

The Honorable Mick Mulvaney  
Director  
Office of Management and Budget  
Washington, D.C. 20503

OFFICE OF WATER

Dear Director Mulvaney:

This letter is in response to the Office of Management and Budget's request for the views and recommendations for Presidential action by the U.S. Environmental Protection Agency (EPA) regarding the enrolled bill S. 3021, America's Water Infrastructure Act of 2018.

The EPA supports signature of S. 3021, which would strengthen the EPA's ability to ensure investment in America's water infrastructure, provide safe drinking water, and protect water quality. The bill would reauthorize the EPA's Drinking Water State Revolving Fund and the Water Infrastructure Finance and Innovation Act programs, which are critical financing tools for updating aging infrastructure and reducing exposure to lead and other contaminants in drinking water systems. The bill would also strengthen a number of Safe Drinking Water Act provisions that will assist the EPA, states, and public water systems in ensuring safe drinking water. Senate bill 3021 would also update and strengthen provisions that enable the EPA to work with states and public water systems to safeguard the nation's drinking water from terrorist acts and natural disasters. Finally, the bill would formally authorize the EPA's WaterSense program, a voluntary partnership program that since 2006 has helped Americans save more than 2.7 trillion gallons of water and \$63.8 billion on utility bills.

For your awareness, S. 3021 would require millions of dollars of additional appropriations and staffing resources for the EPA above FY18 levels to effectively implement the multitude of new and significantly modified Safe Drinking Water Act and Clean Water Act programs authorized in the bill. If you have further questions, please contact me or your staff may contact Matt Klasen in the EPA's Office of Congressional and Intergovernmental Relations at [klasen.matthew@epa.gov](mailto:klasen.matthew@epa.gov) or (202) 566-0780.

Sincerely,

A handwritten signature in blue ink, appearing to read "D. Ross", is positioned below the word "Sincerely,".

David P. Ross  
Assistant Administrator



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

NOV 29 2018

OFFICE OF WATER

The Honorable Mick Mulvaney  
Director  
Office of Management and Budget  
Washington, DC 20503

Dear Mr. Mulvaney:

This letter is in response to the Office of Management and Budget's request for the views and recommendations for Presidential action by the United States Environmental Protection Agency (EPA) regarding the enrolled bill S. 140.

The EPA supports signature of S. 140 which would amend the Clean Water Act to create national discharge standards for ballast water and other discharges incidental to the normal operation of vessels. The bill would phase out the EPA's Vessel General Permit and create a new regulatory framework wherein the EPA would set technology-based discharge standards and Coast Guard would implement and enforce these standards. The bill would also allow states to petition the EPA and Coast Guard to impose more stringent requirements while granting states authority to enforce these federal discharge requirements.

S. 140 would require the EPA to undertake numerous regulatory activities to develop and implement new programs detailed in the bill, including the development of standards of performance for marine pollution control devices. These activities will require additional appropriations and staffing resources beginning this year. The bill would also authorize \$50 million annually for five years for aquatic nuisance species monitoring in the Great Lakes and Lake Champlain regions. This monitoring program would also require additional appropriations for the EPA in FY19. If you have further questions, please contact me or your staff may contact Elizabeth Skane in EPA's Office of Congressional and Intergovernmental Relations at [skane.elizabeth@epa.gov](mailto:skane.elizabeth@epa.gov) or (202) 564-5696.

Sincerely,

A handwritten signature in blue ink, appearing to read "D. Ross", is positioned below the word "Sincerely,".

David P. Ross  
Assistant Administrator



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

♦ ♦

DEC 27 2018

The Honorable Mick Mulvaney  
Director  
Office of Management and Budget  
Washington, DC 20503

OFFICE OF WATER

Dear Mr. Mulvaney:

This letter is in response to the Office of Management and Budget's request for the views and recommendations for Presidential action by the U.S. Environmental Protection Agency (EPA) regarding the enrolled bill H.R. 7279, *Water Infrastructure Improvement Act*.


The EPA supports signature of H.R. 7279, which would amend the Clean Water Act (CWA) to provide for an integrated planning process and to promote green infrastructure.

An integrated plan sequences CWA discharge requirements so the highest priority projects come first. H.R. 7279 requires the permitting authority to inform municipalities of the opportunity to develop an integrated plan, ways in which such a plan may integrate CWA requirements, how the plan may be incorporated into a permit and the use of compliance schedules in permits and enforcement actions related to these integrated plans. In addition, the Agency would be required to prepare and submit a report to Congress on the implementation of integrated plans.

Green infrastructure is an approach to managing wet weather impacts by reducing and treating stormwater at its source. H.R. 7279 further defines green infrastructure and requires the EPA to promote the use of green infrastructure across its CWA implementation activities, including permitting, enforcement, research, information sharing, technical assistance, and funding guidance at both the Headquarters and Regional levels. And, finally, the bill would establish within the Office of the Administrator a municipal ombudsman, who would work with municipalities on available technical and financial assistance.

While the EPA is engaged in some of these activities to a degree, H.R. 7279 would require additional appropriations and staffing resources to support the Report to Congress, the municipal ombudsman, and the expanded use and promotion of both integrated planning and green infrastructure as envisioned by the legislation. If you have further questions, please contact me or your staff may contact Elizabeth Skane in EPA's Office of Congressional and Intergovernmental Relations at [skane.elizabeth@epa.gov](mailto:skane.elizabeth@epa.gov) or (202) 564-5696.

Sincerely,

  
For David P. Ross  
Assistant Administrator



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

DEC 28 2017

OFFICE OF WATER

The Honorable Mick Mulvaney  
Director  
Office of Management and Budget  
Washington, DC 20503

Dear Mr. Mulvaney:

This letter is in response to the Office of Management and Budget's request for the views and recommendations for Presidential action by the United States Environmental Protection Agency (EPA) regarding the enrolled bill S. 2273.

EPA supports signature on this bill, which would extend the previously existing moratorium that exempted all incidental discharges, except ballast water from commercial fishing vessels and non-recreational vessels under 79 feet (hereafter "the moratorium vessels") from having to obtain a Clean Water Act permit. The existing moratorium expired at midnight on December 18, 2017. S. 2273. We recommend the President sign this bill into law extending the previously existing moratorium to January 19, 2018.

Sincerely,

A handwritten signature in black ink that reads "Dennis Lee Forsgren". The signature is written in a cursive, flowing style.

Dennis Lee Forsgren, Jr.  
Deputy Assistant Administrator  
Office of Water





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OCT 15 2018

The Honorable Mick Mulvaney  
Director  
Office of Management and Budget  
Washington, D.C. 20503

OFFICE OF WATER

Dear Director Mulvaney:

This letter is in response to the Office of Management and Budget's request for the views and recommendations for Presidential action by the U.S. Environmental Protection Agency (EPA) regarding the enrolled bill S. 3021, America's Water Infrastructure Act of 2018.

The EPA supports signature of S. 3021, which would strengthen the EPA's ability to ensure investment in America's water infrastructure, provide safe drinking water, and protect water quality. The bill would reauthorize the EPA's Drinking Water State Revolving Fund and the Water Infrastructure Finance and Innovation Act programs, which are critical financing tools for updating aging infrastructure and reducing exposure to lead and other contaminants in drinking water systems. The bill would also strengthen a number of Safe Drinking Water Act provisions that will assist the EPA, states, and public water systems in ensuring safe drinking water. Senate bill 3021 would also update and strengthen provisions that enable the EPA to work with states and public water systems to safeguard the nation's drinking water from terrorist acts and natural disasters. Finally, the bill would formally authorize the EPA's WaterSense program, a voluntary partnership program that since 2006 has helped Americans save more than 2.7 trillion gallons of water and \$63.8 billion on utility bills.

For your awareness, S. 3021 would require millions of dollars of additional appropriations and staffing resources for the EPA above FY18 levels to effectively implement the multitude of new and significantly modified Safe Drinking Water Act and Clean Water Act programs authorized in the bill. If you have further questions, please contact me or your staff may contact Matt Klasen in the EPA's Office of Congressional and Intergovernmental Relations at [klasen.matthew@epa.gov](mailto:klasen.matthew@epa.gov) or (202) 566-0780.

Sincerely,

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David P. Ross  
Assistant Administrator